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UNITED STATES DISTRICT COURT  
 SOUTHERN DISTRICT OF NEW YORK

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 IN RE: :  
 Fosamax Products Liability Litigation : 1:06-md-1789 (JFK)  
 :  
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*This Document Relates to:* : **ANSWER AND AFFIRMATIVE**  
 Angelarose Mione : **DEFENSES OF MERCK**  
 v. Novartis Pharmaceuticals Corp. and : **& CO., INC.;**  
 Merck & Co., Inc. : **DEMAND FOR JURY TRIAL**  
 Case No: 07-cv-02956-JFK :  
 -----X

Defendant Merck & Co., Inc. ("Merck"), by its undersigned attorney, answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

1. Merck admits that Plaintiff purports to bring a civil action for damages. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations against Novartis. Merck denies the remaining allegations of Paragraph 1.

**PARTIES**

2. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of Paragraph 2.

3. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 3.

4. Merck admits the allegations of Paragraph 4.

5. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations against Novartis in Paragraph 5. Merck denies the remaining allegations of Paragraph 5.

### **JURISDICTION**

6. The allegations contained in Paragraph 6 are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph, except that for jurisdictional purposes only, admits that the amount in controversy exceeds \$75,000.00.

### **FACTUAL BACKGROUND**

7. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 7.

8. Merck refers the Court to the prescribing information for Zometa, and denies any allegations in Paragraph 8 with respect to Zometa inconsistent with that prescribing information.

9. Merck refers the Court to the prescribing information for Zometa, and denies any allegations in Paragraph 9 with respect to Zometa inconsistent with that prescribing information.

10. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 10.

11. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 11.

12. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 12, except that it admits that Ruggiero, et al., published an article entitled, “Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 Cases,” Journal of Oral and Maxillofacial Surgery, vol. 62, p. 533 (2004) and respectfully refers the Court to said article for its actual language and full text.

13. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 13.

14. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 14.

15. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 15.

16. Merck denies each and every allegation of Paragraph 16, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX®.

17. Merck admits that FOSAMAX® is a prescription medication approved by the federal Food and Drug Administration (“FDA”) for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 17 inconsistent with that prescribing information.

18. Merck admits that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 18 inconsistent with that prescribing information.

19. Merck denies each and every allegation of Paragraph 19.

20. Merck denies each and every allegation of Paragraph 20.

21. Merck denies each and every allegation of Paragraph 21.

22. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 22.

23. Merck denies each and every allegation of Paragraph 23.

24. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 24 and subparts (a) through (g).

25. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the statement that Plaintiff took FOSAMAX®. Merck denies each and every remaining allegation of Paragraph 25 and subparagraphs (a) through (g).

**FIRST CLAIM FOR RELIEF**  
**[Strict Product Liability – Design Defect]**

26. Merck repleads its answers to Paragraphs 1 through and including 25, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

27. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 27.

28. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 28.

29. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 29.

30. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 30.

31. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 31.

32. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 32.

33. Merck denies each and every allegation of Paragraph 33, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX®.

34. Merck denies each and every allegation of Paragraph 34.

35. Merck denies each and every allegation of Paragraph 35.

36. Merck denies each and every allegation of Paragraph 36.

37. Merck denies each and every allegation of Paragraph 37.

38. Merck denies each and every allegation of Paragraph 38.

**SECOND CLAIM FOR RELIEF**  
**[Strict Product Liability – Failure to Warn]**

39. Merck repleads its answers to Paragraphs 1 through and including 38, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

40. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 40.

41. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 41.

42. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 42.

43. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 43.

44. Merck denies each and every allegation of Paragraph 44, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX®.

45. Merck denies each and every allegation of Paragraph 45.

46. Merck denies each and every allegation of Paragraph 46.

47. Merck denies each and every allegation of Paragraph 47.

**THIRD CLAIM FOR RELIEF**  
**[Negligence]**

48. Merck repleads its answers to Paragraphs 1 through and including 47, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

49. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 49.

50. The allegations contained in Paragraph 50 are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 50.

51. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 51.

52. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 52.

53. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 53.

54. Merck denies each and every allegation of Paragraph 54, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX®.

55. The allegations contained in Paragraph 55 are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.

56. Merck denies each and every allegation of Paragraph 56.

57. Merck denies each and every allegation of Paragraph 57.

58. Merck denies each and every allegation of Paragraph 58.

**FOURTH CLAIM FOR RELIEF**  
**[Breach of Express Warranty]**

59. Merck repleads its answers to Paragraphs 1 through and including 58, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

60. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 60.

61. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 61.

62. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 62.

63. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 63.

64. Merck denies each and every allegation of Paragraph 64, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

65. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 65.

66. Merck denies each and every allegation of Paragraph 66.

67. Merck denies each and every allegation of Paragraph 67.

**FIFTH CLAIM FOR RELIEF**  
**[Breach of Implied Warranty]**

68. Merck repleads its answers to Paragraphs 1 through and including 67, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

69. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 69.

70. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 70.

71. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 71.



72. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 72.

73. Merck denies each and every allegation of Paragraph 73, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

74. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 74.

75. Merck denies each and every allegation of Paragraph 75.

76. Merck denies each and every allegation of Paragraph 76.

#### **PRAYER FOR RELIEF**

Merck denies that Plaintiff is entitled to any of the relief requested in her Prayer for Relief.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

#### **AFFIRMATIVE DEFENSES**

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as may be appropriate. Further, Merck reserves the right to amend

its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

**FIRST AFFIRMATIVE DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

**SECOND AFFIRMATIVE DEFENSE**

The Complaint fails to state a claim upon which relief can be granted.

**THIRD AFFIRMATIVE DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

**FOURTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

**FIFTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

**SIXTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®,

such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

**SEVENTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were cause in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

**EIGHTH AFFIRMATIVE DEFENSE**

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by the application of the doctrine of comparative fault and/or negligence.

**NINTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

**TENTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

**ELEVENTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

**TWELFTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

**THIRTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.

**FOURTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**FIFTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

**SIXTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff seeks punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**NINETEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

**TWENTIETH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part by failure to mitigate damages.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

With respect to each and every cause of action, Plaintiff is not entitled to recovery for strict liability because Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of action.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to unfair or deceptive practices are barred.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States and New York Constitutions.

**THIRTIETH AFFIRMATIVE DEFENSE**

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

**THIRTY-FIRST AFFIRMATIVE DEFENSE**

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available

medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

**THIRTY-SECOND AFFIRMATIVE DEFENSE**

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

**THIRTY-THIRD AFFIRMATIVE DEFENSE**

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

**THIRTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiff has not sustained an ascertainable loss of property or money.

**THIRTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiff has not suffered any actual injury or damages.

**THIRTY-SIXTH AFFIRMATIVE DEFENSE**

Plaintiff's claimed are barred under the doctrine of economic loss.

**THIRTY-SEVENTH AFFIRMATIVE DEFENSE**

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

**THIRTY-EIGHTH AFFIRMATIVE DEFENSE**

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).



**THIRTY-NINTH AFFIRMATIVE DEFENSE**

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

**FORTIETH AFFIRMATIVE DEFENSE**

Merck is entitled to a set-off or reduction in any damages which may be awarded to the Plaintiffs for any amounts received from collateral sources.

**FORTY-FIRST AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

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Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing the Complaint with prejudice and awarding Merck its reasonable costs and disbursements, including reasonable attorneys' fees, together with such and other and further relief that the Court may deem just and proper.

**JURY DEMAND**

Merck demands a trial by jury as to all issues so triable.

DATED: New York, New York  
May 9, 2007

Respectfully submitted,

HUGHES HUBBARD & REED LLP

By: /s/  
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